Connecticut College

Digital Commons @ Connecticut College

CISLA Senior Integrative Projects

Toor Cummings Center for International Studies and the Liberal Arts (CISLA)

2020

Social, Economic, and Political Aspects of the Healthcare Systems in Italy and the United States

Conor O'Neil
Connecticut College, coneil1@conncoll.edu

Striving for the Perfect Healthcare System: A Comparative Study of Systems in Italy and the United States with a Focus on Diabetes

Conor O'Neil, Advisor: Professor Marc Zimmer
Connecticut College 2020,
Spring Semester 2020 IS 492

Foreword:

During the past academic year and over the past summer I had the privilege of being involved in working with the Italian health care system for 2 months. I regularly engaged with doctors, residents, patients, and Italian citizens. Through my time in Italy I have recognized many inspiring people from all over the country who are determined to provide the best care possible to the patients they serve. Gaining knowledge from my experiences being involved in the health care system in Italy, as well as the people who reside there, I plan to address the treatment of diabetes within the healthcare systems in Italy and the United States.

As a CISLA Scholar from Connecticut College, a small liberal arts college on the east coast of the United States, I have been prepared through Italian classes improving my language skills, global perspective classes teaching that different cultures have varying was of viewing the world, and biology and chemistry classes to help me understand the human body function in relation to medicine. In preparation for this analysis I have examined data surrounding the cost and quality of care for the management of type 1 diabetes. The underlying constant was that although changes may be suggested, both Italian and United States health care systems do not rapidly change and is quite rare for either to dramatically change the system as a whole. Drawing from this data I will compare aspects of the two health systems from the two countries in search for improvements. As Samuel Johnson said “All travel has its advantages. If the passenger visits better countries, he may learn to improve his own. And if fortune carries him to worse, he may learn to enjoy it.”

I’d like to give a special thank you to the CISLA program for funding the opportunity to work in Italy, my CISLA peers for supporting each other, my advisor Professor Marc Zimmer, as well as Mary Devins, Cara Masullo, Betsy Lebel, Professor Marc Forster and Professor Lanoux for supporting me in my studies since sophomore year.

Table of Contents

I. *The Italian Healthcare System*

The National Health Service of Italy, or Servizio Sanitario Nazionale (SSN) in Italian, was created on December 23rd, 1978 and founded on the values of social financing through general taxation, free of charge universal coverage, and non-discriminatory access to healthcare services. The SSN was solidly integrated into the nation's constitution when 85% of Parliament agreed to enact the SSN. This ensures that every Italian in need of healthcare receives the service they need.

The stated values of the SSN are “High quality healthcare for all Italians, universality, equity, and solidarity, (to be) at the first ranks in the world for healthy life expectancy, life expectancy among the best in Europe, leader in Europe for the number of free drugs, the excellence in transplants, the pediatrician free for all children, front runners in high-tech diagnostics, decreasing hospital infections, healthcare quality and safety standards, and prevention, to be healthy and avoid illness.” (Ministero della Salute, 2019)

The current healthcare system of Italy is considered a regional based national health service (World Health Organization, 2020), while the central government controls the distribution of tax revenue for publicly financed health care. The central government is also responsible for defining the national statutory benefits package to be offered to all residents from every region. For background, there are 19 regions and two autonomous provinces that have the responsibility to organize and deliver healthcare services through local and regional health units (Hospital, House, etc.) (Donatini, 2016). Regional healthcare systems can vary because of the region's ability to determine the macrostructure of their own healthcare systems.

The SSN is designed to publicly finance the healthcare of all citizens and legal foreign residents, with coverage being automatic and universal. In 2014, public financing accounted for 75.8% of total healthcare spending, with the total expenditure being 9.1% of the GDP. The total GDP being 1.787 trillion euro in 2019 according to the Federal Reserve Bank of St. Louis. This public healthcare system is financed through a national corporate tax, 35.6% in 2012, that is allocated back to regions based on the proportion to the regions contribution. The less a region contributes to the tax, the less money it receives back leading to financial inequalities between regions (Donatini, 2016). Another big financial contributor to the public healthcare system is a fixed proportion of national value-added tax revenue, 43.7% in 2012, collected by the central government and redistributed to regions who do not have resources to provide essential levels of care.

Each region of Italy generates their own additional revenue creating even further financial gaps to fund the regional units. To help mitigate this issue there is a Standing Conference on Relations between the State, Regions, and Autonomous Provinces to set the criteria, usually population size and age demographics, to allocate funding to regions through a capitated budget. The SSN does not allow people to opt out and seek only private care, however supplementary private health insurances are available (Donatini, 2016).

Primary care and inpatient care are free upon visitation. Italy creates positive and negative lists based upon medical necessity, effectiveness, human dignity, appropriateness, and efficiency in delivery. Positive lists identify services offered to all residents like pharmaceuticals, while negative lists identify services that are not offered to patients like cosmetic surgery.

Prescription drugs have been divided into 3 tiers according to clinical effectiveness and cost effectiveness. “Classe A” drugs are lifesaving drugs and treatments for chronic conditions and are fully covered in all cases. “Classe C” drugs contain all other drugs not covered and “classe H” drugs can only be delivered in a hospital setting.

There are no charges for a general practitioner visit and hospital stays. However, there are copayments up to EUR36.15 for each specialist visit or prescribed procedure. To combat the rising public debt, the government has applied an additional EUR10 copayment for each prescription, as well as a EUR25 for unnecessary use of emergency services (some regions have not invoked this copayment). There are no other deductibles and both public and private sectors have contractual agreements with the SSN to not charge above the scheduled fees. Individuals with out-of-pocket expenses over EUR129 in a year are eligible for a tax credit equal to roughly one-fifth of their spending and there are no caps.

The main out of pocket expenses are mainly for drugs not covered by the public system and for dental care. These kinds of drugs are mainly “classe C”. Out of pocket expenses accounted for 22% of the individual’s total health care spending in 2015. To ensure the fairness costs for the Italian citizens there are exemptions from cost-sharing that are made for people under age 6 and over 65 who live in a household with income below EUR36,000, which is the nationally defined threshold. Prisoners and people with severe disabilities are exempt from all cost sharing. Pregnant women and people with chronic or rare diseases are all exempt from cost-sharing related to treatment. Additionally, many screening services are provided free of charge.

Table 1. Demographics and Health Risk Factors in Italy (2014).

Total Population (millions)	Percentage of People of Population 65 and older	Percentage of Adults who Report being Daily Smokers	Prevalence of Obesity (BMI > 30)
60.8	21.4%	20%	10%

(Donatini, 2016).

Table 2. Health System Statistics in Italy (2014).

Health Care Spending per Capita	Out-of-Pocket Health Care Spending	Number of Practicing Physicians per 1,000 Population	Hospital Spending per Discharge	Primary care Physician’s use of Electronic Medical Records
$3,207	$706	3.9	$12,150	N/A

(Donatini, 2016).

Tables 1 and 2 highlight the factors affecting the healthcare system in Italy. Table 1 displays the statistics of people in the at-risk populations. This list is in stable condition but can always be lower. One highlight not to be overlooked is the aging and elderly population that requires more health care. Table 2 shows the amount of money individuals pay for health care, amount of practicing physicians, and hospital spending upon discharge. The number of physicians is small but almost double per 1,000 people than in the United States. The amount of money the hospitals spend per discharge is also smaller than in the United States, still the system would benefit from less hospitalizations based on these numbers. Figure 1 below is the organization behind the health system in Italy.

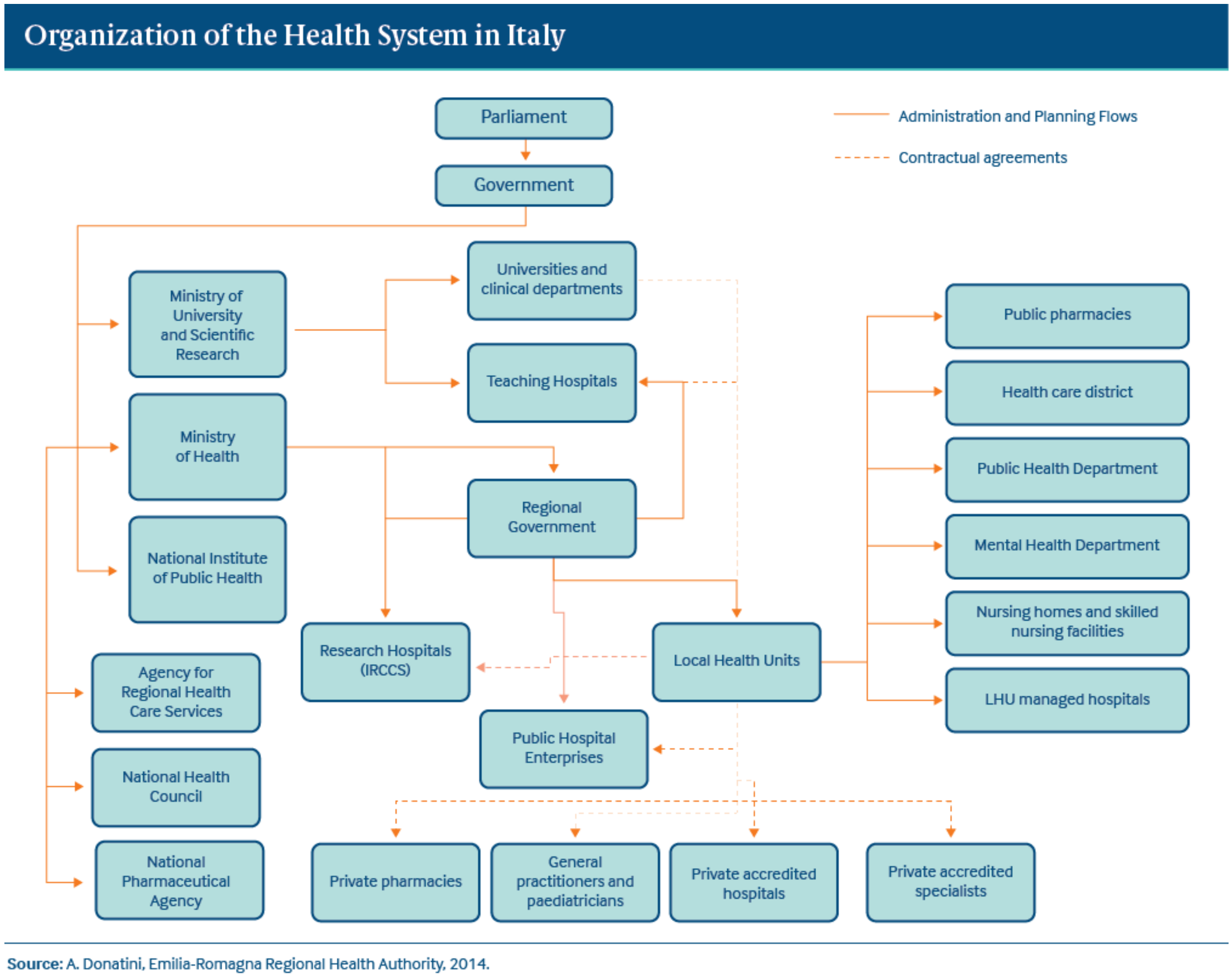


Figure 1. Organization of the Health System in Italy. The bold orange line represents administrative prowess and the dotted orange line represents contractual agreements between the health sectors. The Ministry of Health has been divided into 12 boards to have an overview of specific fields of health care (essential levels of care and health system ethics; human resources and health professionals; information systems; pharmaceuticals and medical devices; and health care planning) or supervise the main institutions related to the Ministry of Health such as the National Health Council or National Institute of Public Health.

II. The United States Healthcare System

Currently, there is no national health care system in the United States, however recently the government has been working towards a more centralized healthcare system. The health coverage in the United States has changed since 2010 with the introduction of the Affordable Care Act (ACA), establishing a “shared responsibility” between the government, employers, and individuals to access affordable health care (The Commonwealth Fund, 2020).

There were 3 main objectives at the time of introduction: (1) to reform the private insurance market, especially for individuals and small-group purchasers, (2) to expand Medicaid to the working poor with income up to 133% of the federal poverty level, and (3) to change the way that medical decisions are made. These objectives however have nearly no influence from governmental regulation, but rather rely primarily on private choices (Silvers, 2013). These private choices are given with the expectation that rational decision making that is shaped by incentives, but free of other constraints will occur. The assumption is that individuals and groups will make rational decisions to produce quality access to medical care at an appropriate price financed through fair risk sharing across a large group of people, leading to affordable care.

Health coverage remains fragmented, with many different private and public sources of health coverage, and large gaps between insured rates within the United States population. Medicare, a federal program for adults aged 65 and older, as well as some people with disabilities, is administered by Medicare and Medicaid Services (CMS). The CMS works in partnership with state governments to administer Medicare and Children’s Health Insurance Program (CHIP), a conglomerate of state-federal programs for low income populations.

United States Presidents Harry S. Truman, John F. Kennedy and Bill Clinton all made attempts at a government-sponsored universal health care, but these attempts never came to fruition. Despite past efforts failing, President Obama was able to plan and put in action the ACA, a government sponsored health care on March 23, 2010. Even though the ACA is government sponsored, there still is no form of universal coverage, although it did help to drop the number of uninsured from around 18% prior to the ACA to around 10% currently (Berchick *et al*. 2019). Private insurance still dominates in the healthcare market as the most prominent way to pay for health care costs. Private insurance is regulated at the state level for the most part.

In 2018 private health insurance coverage covered 67.3% of the United States population, while public health insurance covered 34.4% of the population. Of all the subtypes of health insurance coverage, employer-based insurance remained the most popular covering 55.1% of the population. The percentage of the population with health insurance in 2018 was 91.5%, lower than the percentage in 2017 by about 0.6%. The percentage of private health insurance remained the same, while those with public coverage dropped between the two years. As of 2018, 8.5% of the population, or 27.5 million people did not have health insurance. In addition, the number of uninsured children under the age of 19 increased by 0.6% between the years. Medicaid coverage dropped by 0.7 percentage points, while Medicare coverage rose 0.4 percentage points (Berchick, 2019).

The ACA has been in place since 2014 and has worked to increase the number of insured in the United States, however the situation surrounding the ACA has been changing since the introduction of the Trump administration. As of right now the ACA is still in effect, however there is uncertainty of how long it will be around as the Trump administration has promised to repeal this act. This is because the new administration is focused on lowering the rising national debt that the more publicly integrated health system the United States had been working to create (Anderson, 2018).

Prior to the initiation of the ACA in 2014, most states had individual coverage medically underwritten. This means that previously, medical coverage was only available to purchase for patients who were healthy, if a patient was unhealthy and looking to purchase insurance they would have a much tougher time. This made it especially difficult for those with chronic illnesses. The insurance companies investigated medical histories upon application, and if they did not like what they saw, they would not accept you. Also, those who purchased health insurance prior to 2014 were required to pay the whole premium on insurance themselves.

In the current version of the ACA, it requires all health plans being offered in the individual market and small-group marker (50 or fewer employees) to cover services in 10 essential health benefit categories (1) ambulatory patient services, (2) emergency services, (3) hospitalization, (4) maternity and newborn care, (5) mental health and substance use disorder treatment, (6) prescriptions, (7) rehabilitative services and devices, (8) laboratory services, (9) preventive and wellness services and chronic disease management, and (10) pediatric services. The individual states determine the range of specific services and how much they cover in each of the ten categories through the selection of a benchmark plan. This makes it so each state's health coverage varies somewhat.

Table 3. Demographics and Health Risk Factors in the United States (2014)

Total Population (millions)	Percentage of People of Population 65 and older	Percentage of Adults who Report being Daily Smokers	Prevalence of Obesity (BMI > 30)
321.19	14.5%	13%	38%

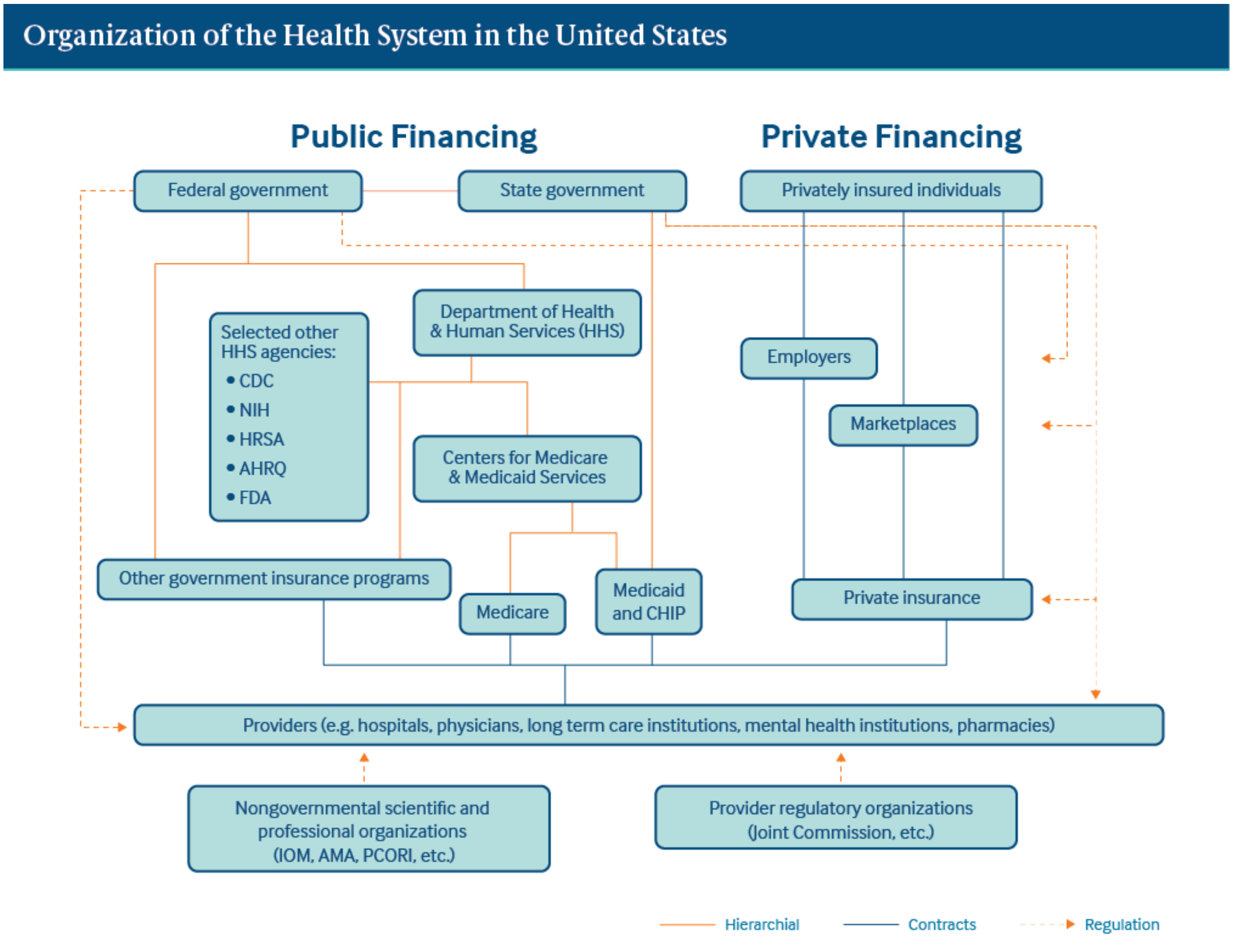
(The Commonwealth Fund, 2020).

Table 4. Health System Statistics in the United States (2014)

Health Care Spending per Capita	Out-of-Pocket Health Care Spending	Number of Practicing Physicians per 1,000 Population	Hospital Spending per Discharge	Primary care Physician's use of Electronic Medical Records
$9,364	$1,034	2.6	$21,603	84%

(The Commonwealth Fund, 2020).

Tables 3 and 4 highlights the factors affecting the healthcare system in the United States. Table 3 displays the statistics of people in the at-risk populations. This list is growing each year with obesity on the rise and the population over 65 growing as well. Table 4 encaptures the amount of money individuals pays for health care, amount of practicing physicians, and hospital spending. The number of primary physicians is small for the amount of people living in the United States and the amount of money the hospitals spend per discharge is very large. The system would benefit from less hospitalizations based on these numbers. Figure 2 below is the organization behind the health system in the United States.



Source: Adapted from T. Rice, P. Rosenau, L. Y. Unruh et al., "United States of America: Health System Review," *Health Systems in Transition*, vol. 15, no. 3, 2013, p. 27.

Figure 2. Organization of the United States Health Care System. The orange dotted lines represent one organization having a form of regulation over another organization. The orange solid line represents how an organization has hierarchical rule over another. The solid blue lines represent contracts between two organizations.

III. What is Diabetes?

After eating a meal, the human body breaks down carbohydrates from foods like bread into various sugar molecules, one of which is glucose, the main energy source for the body. Glucose is absorbed into the bloodstream, then to be absorbed by cells along with the help of a hormone that the body produces. This hormone is called insulin and it is what allows the body to take glucose from the bloodstream and move it into the cells of the body. In type 1 diabetes, the body no longer produces insulin, while in type 2 diabetes the body no longer uses insulin properly, does not make enough insulin or the body has become desensitized to insulin.

Type 1 diabetes is known as insulin-dependent diabetes and is typically diagnosed in children and young adults but can develop at any age. Insulin is produced by the pancreas and without insulin, glucose builds up in the bloodstream and causes complications in the body. Type 1 diabetes is less common than type 2 diabetes, occurring in 5-10% of people living with diabetes. Type 1 diabetes is caused by an autoimmune reaction that destroys the insulin-producing beta cells in the pancreas. This will go on for a few months or even years before any symptoms appear. Genes can be passed on from parents to children to make them more likely to develop type 1 diabetes. Being exposed to triggers in the environment, like a virus, can play a role in the development of type 1 diabetes, while diet and lifestyle habits don’t play as much of a role in causing type 1 diabetes (Center for Disease Control and Prevention, 2020). Currently, there is no known way to prevent type 1 diabetes, but it can be managed properly following a healthy lifestyle and diet, regular exercise, controlling blood glucose with insulin injections, knowing how to recognize high or low blood glucose levels, and obtaining and storing diabetes supply properly.

Type 2 diabetes used to be called adult-onset diabetes, however, this has changed as more and more children are being diagnosed with type 2 diabetes each year. Type 2 diabetes is a chronic condition in which the body either resists the effect of insulin or does not produce enough insulin to maintain normal blood glucose levels. The causes are known to be related to genetics and environmental factors. There is also no known cure like type 1, but it can be managed in the same ways.

People living with diabetes must pay attention to blood glucose levels to prevent hypoglycemia and hyperglycemia. Normal blood sugar levels can vary for adults but are typically considered to be 70-130 mg/dL (Center for Disease Control and Prevention, 2020). Hypoglycemia is the condition of low levels of blood glucose. This can happen because of the intake of too much insulin, waiting too long for a meal or snack, not eating enough, or getting extra physical activity resulting in the body using that glucose to make ATP. This needs to be treated immediately as there are severe complications and can lead to a diabetic coma. Symptoms can include shakiness, nervousness, sweating, chills, irritability, dizziness, hunger, weakness, anger, or sadness. Symptoms can be different from person to person. Hyperglycemia is the condition of high levels of blood glucose, usually above 180-200 mg/dL. This can be triggered by foods, illness, medication that is not treating diabetes, or not injecting enough insulin. It is important to treat hyperglycemia because it can lead to complications like a diabetic coma, ketoacidosis, and if persistent in the long-term lead to complications with the body's eyes, kidney, nerves, and heart. Symptoms include frequent urination, increased thirst, blurred vision, fatigue, and headaches (Center for Disease Control and Prevention, 2020).

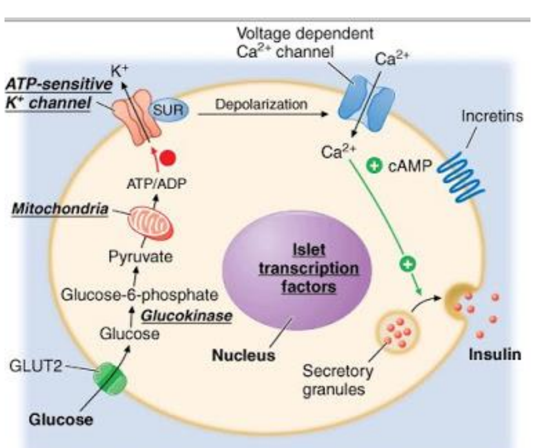
Prediabetes is a serious health condition of elevated blood glucose levels but is not high enough to be completely diagnosed as type 2 diabetes. 88 million adults living in the US, more than 33% of American adults, have prediabetes (Center for Disease Control and Prevention, 2020).

Long term complications of diabetes are important to understand. In general, the longer a person has diabetes and the less controlled your blood sugar, the higher the risk of encountering complications. Diabetes complications can be disabling or even life-threatening. Diabetes dramatically increases the risk of various cardiovascular problems, including coronary artery disease, heart attack, stroke, and atherosclerosis. When there is excess glucose into the blood, it can injure capillaries that nourish your nerves, especially in the legs and feet. Blood glucose levels that are out of the ordinary can cause damage to the glomeruli, which are tiny blood vessel clusters in the kidney, damaging the system that filters waste from your blood in the kidney. Additionally, eye and feet problems are more common in people who have diabetes (Center for Disease Control and Prevention, 2020). The international diabetes federation has estimated that around 8.3% of adults are living with diabetes, and in less than 20 years that number will most likely rise above half a billion (Himabindu, 2015).

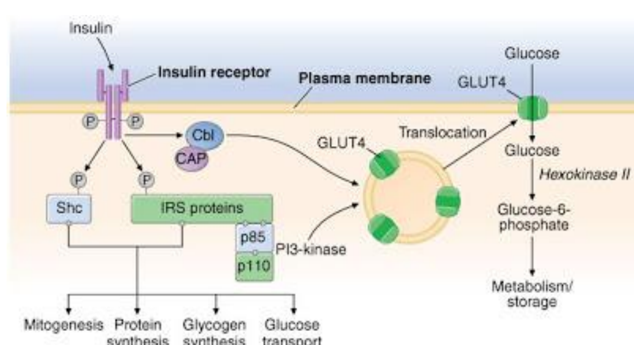
Molecular Description of Disease

Regulation of blood glucose levels is important because there are many complications that can stem from mismanagement of blood glucose levels. The three main hormones that control blood glucose levels are insulin, glucagon, and epinephrine.

Insulin is synthesized as preproinsulin and later processed to proinsulin. The proinsulin is converted to insulin and stored in secretory granules awaiting the signal to be released. The synthesis of insulin is regulated at both the transcriptional and translation level. The transcription is regulated by the cis-acting sequences in the 5’ flanking region and by trans-activators like paired box gene 6 (PAX6), the pancreatic and duodenal homeobox-1 (PDX-1), MafA, and B-2/Neurogenic differentiation 1 (NeuroD1). The stability of preproinsulin mRNA, along with its untranslated regions control protein translation (Fu *et al*. 2014). Insulin is released by the beta cells in the islets of Langerhans residing in the pancreas when glucose concentrations are high, leading to ATP being made by the citric acid cycle. There is a fusion of secretory granules with the plasma membrane allowing the insulin to be released with intracellular [Ca^{2+}] being the primary insulin secretory signal, with cAMP signaling dependent mechanisms being important to regulation of secretion as well. In addition, free fatty acids and amino acids can augment glucose-induced insulin secretion (Fu, 2014). The beta cells can be considered a metabolic hub that links nutrient metabolism and the endocrine system. Insulin travels through the bloodstream and to muscle, brain, or adipose tissue. Once it arrives it binds to an insulin receptor activating further metabolic pathways resulting in glucose flowing from the bloodstream and into cells through the GLUT4 protein (Röder *et al*. 2016). The insulin transduction pathway can be observed below in Figure 3.



(a)



(b)

Figure 3. (a) Glucose stimulated insulin secretion. Glucose enters the cell through the GLUT2 transporter leading to the production of pyruvate. The pyruvate is then used to create ATP that binds to an ATP-sensitive channel causing the release of K^+ and depolarization. Voltage dependent Ca^{2+} channel is then opened causing a rise in cAMP and the release of insulin from secretory granules. (b) Insulin signal transduction pathway in skeletal muscle. Insulin binds to the insulin receptor and then interacts with the Shc and IRS pathways through phosphorylation increasing mitogenesis, protein synthesis, glycogen synthesis and glucose transport. The Cbl and PI3-kinase cause translocation of the GLUT4 receptor to the membrane to allow glucose into the cell (Jameson *et al*. 1998).

Glucagon acts when blood glucose levels are low to inhibit the breakdown of glucose and activates gluconeogenesis, the creation of more glucose from pyruvate, lactate, glycerol, and amino acids. The glucose that is made is released into the bloodstream to increase blood glucose levels. Glucagon is released from the alpha cells in the islets of the pancreas. Glucagon primarily operates in the liver (Röder, 2016).

Epinephrine is released when the brain encounters flight or fight situations. Epinephrine tells the body to increase heart rate, cause bronchial dilation, and glucose release in a prolonged response. Epinephrine is released from the adrenal glands. This works to increase the amount of glucose in the blood, which can supply cells to then produce more ATP to meet the body's increased energy requirements (Röder, 2016).

Type I diabetes is a complex disorder resulting in multiple genes and environmental factors acting to cause the autoimmune attack. In monogenic type 1 diabetes IPEX (immune, dysfunction, polyendocrinopathy, enteropathy, X-linked), the disease is caused by a single gene defect in the FOXP3 gene (Ali, 2010). The mutation leads to a lack of regulatory T lymphocytes that results in autoimmunity in 80% of the cases and development of diabetes as early as 2 years of age. Additionally, in the monogenic APS-I syndrome (autoimmune polyendocrinopathy syndrome type 1) there is a single gene mutation of the AIRE (autoimmune regulator) gene (Ali, 2010). This leads to abnormal expression of peripheral antigens in the thymus and abnormal negative selection in the thymus resulting in widespread autoimmunity. 18% of children with the gene defect develop diabetes.

In most cases of diabetes, the disease is not due to a single gene defect but rather caused by the influence of several risk loci. The region with the greatest risk contribution of type 1 diabetes is the major histocompatibility complex on chromosome 6 (Ali, 2010). Another region that shows up in genetic studies of the disease quite a bit is the promoter region 5' of the insulin gene on chromosome 11 (Ali, 2010). More recent studies show that the PTPN22 gene on chromosome 1 has a large contribution to the disease, the question now is how these multiple genes interact together to bring about observed the autoimmune response.

Type 2 diabetes is complex resulting from environmental and genetic factors. The common polygenic form of type 2 diabetes, that is the late-onset form, results from an early-onset of resistance to insulin paired with functional defects in insulin secretion by beta cells in pancreatic islets (Kulkarni and Kahn, 2004). The precise factors leading to the late-onset form are unknown. The monogenic form of diabetes, known as maturity-onset diabetes of the young (MODY), has been studied and is known to be caused primarily by defects affecting the functioning of islet beta cells. There are six forms of MODY. MODY2 is caused by mutations in the glucokinase gene. MODY4 and MODY6 are known to be caused by mutations in genes that encode for the pancreatic homeodomain transcription factor PDX-1 and another transcription factor that is required for normal development of the pancreatic islet beta cells called NeuroD1 and BETA2. Meanwhile, MODY1, MODY3, and MODY5 are all caused by mutations in genes that encode for hepatocyte nuclear family (HNF) transcription factors being HNF4[alpha], HNF1[alpha], and HNF[beta] respectively (Kulkarni and Kahn, 2004). Kulkarni and Kahn cite that there has been a genome-scale analysis of genes that are regulated by three HNF transcription factors in both liver and pancreatic islet tissue. This analysis showed a link between the common late-onset type 2 diabetes and a defect in HNF4[alpha], with this defect possibly being a large contributor to the disease (Kulkarni and Kahn, 2004). The question now to ask is what other factors are affecting the pancreatic and liver islet tissue.

Insulin Delivery and Blood Glucose Monitoring Technology

Insulin can be delivered into the human body in a multitude of ways. Insulin syringes and pens are one of the most common and oldest ways of delivering insulin. Insulin syringes are used in combination with a vial of insulin. The syringe takes up the insulin from the vial and can safely and effectively deliver the insulin to the glycemic target. Insulin syringes should be used once an injection, unfortunately in resource limited environments individuals reuse the syringe which can lead to infections. When a needle is reused, it is dulled and causes more pain to the user upon injection. Needle thickness and length needs to be considered for every patient as well. The thicker the needle, the more insulin can be delivered per injection, but there is also more pain. Studies have shown that a shorter needle helps to prevent intramuscular injections (American Diabetes Association, 2018).

Insulin pens offer the added convenience of combining the vial and syringe into a single device, oftentimes costing more than just a syringe. A pen can be disposable with prefilled cartridges or reusable with replaceable insulin cartridges. As technology has progressed, “smart” pens have come about. A smart pen can be programmed to calculate insulin doses and downloadable data reports are available.

Insulin pumps have been available for around 40 years now. They can deliver rapid acting insulin throughout the day to manage blood glucose levels. Insulin pumps use tubing to deliver the insulin into the body. There are modest advantages of using a pump such as not having to inject a needle after each meal and helping to reduce severe hypoglycemia rates in children and adults.

Adoption of pump therapy shows geographic variation in both Italy and the United States. This may be related to provider preference, but more than likely reflects socioeconomic status. Pump therapy is more common in individuals of higher socioeconomic status based upon race, ethnicity, family income, regional income, and education (American Diabetes Association, 2018). As seen in Table 5, the urban patients are typically seen to use the pump more often, while less often rural youth have a pump. This is because of lower income and longer distances to travel for regular checkups on the pump. Seen in Figure 4, some states may not even provide any coverage for diabetic care, making it much more difficult for diabetics to receive technology like a pump. This is very similar to how some regions receive better healthcare than others in Italy. Some disadvantages to pump therapy include dislodgement of the pump placing patients at risk for ketosis and pump site activation. Also, some people have problems with having a pump attached to them based upon looks and discomfort, instead preferring injections.

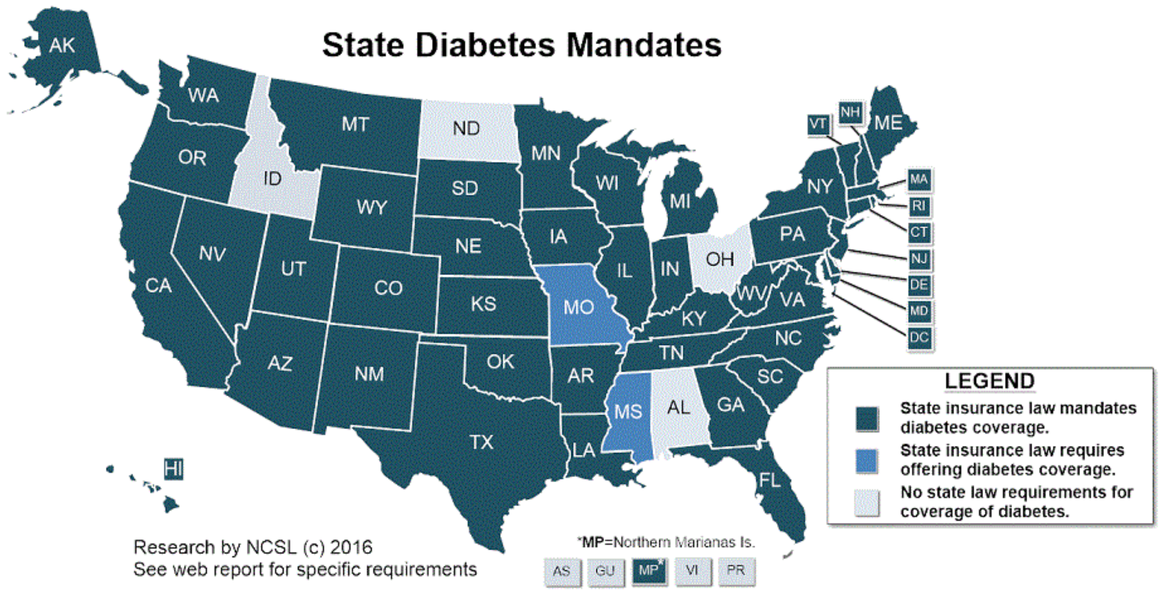


Figure 4. State mandated insurance coverage for diabetes in the United States (Cauchi *et al*. 2016).

Table 5. Demographics of diabetes treatment (Stumetz *et al*. 2016).

Demographic/Clinical characteristics	Total sample (n=61)	Rural 56% (n=34)	Urban 44% (n=27)
Age of participating youth (mean+/-SD)	13.3 +/- 3.4	13.2 +/- 3.4	13.5 +/- 3.6
Race (% Non-Hispanic Whites)	85%	74%	93%
Education level of caregiver (>high school)	68%	63%	74%
Family income (% <50K/year)	36%	47%	22%
Public insurance	38%	56%	15%
HbA1c (mean+/-SD)	8.8 +/- 1.7	9.0 +/- 1.8	8.5 +/-1.6
Insulin regime (% pump)	54%	47%	63%

Diabetics need to self-monitor their blood glucose to ensure proper levels. Glucose meters are a common way of measuring blood glucose. Interestingly, currently marketed glucose meters in Italy and the rest of Europe have to meet the current International Organization for Standardization, while monitors marketed in the United States must meet the standard under which they were improved, which is not the current standard leading to many people getting less than the standards require. In addition, monitoring of the accuracy of the meters in the United States is left to the manufacturer and not often checked by an independent source.

A newer form of blood glucose monitoring is the use of a continuous glucose monitor (CGM). The CGM allows patients to evaluate their blood glucose responses to blood sugar levels through a tablet device or even a cell phone. This can be used in combination with a diabetic pump to allow for insulin delivery through the click of a button on the phone. This is a huge step in working towards preventing hypoglycemia and hyperglycemia, as well as further complications stemming from such instances. This could help improve the safety of diabetics, as well as drive their individual and hospital costs.

IV. Prevalence of Diabetes in Italy

ISTAT has been keeping track of the prevalence of diabetes in Italy since as far back as 1980. As of 2016, 5.3% of the population had diabetes equaling up to 3.2 million people. The amount of the population living with diabetes has nearly doubled from 2.9% of the population in 1980. ISTAT has identified this increase is because the life expectancy of those living with diabetes has increased, early diagnosis of diabetes, and aging of the population, all signs of a good health system. ISTAT also reports that mortality from diabetes has decreased by 20% across all age groups in the last decade from 2006 to 2016.

According to a study published in *Nutrition, Metabolism and Cardiovascular Diseases* population-based registries of both in Europe and the United States have evidence of type 1 diabetes increasing somewhere between 2.8%-4% per year (Bruno *et al*. 2016). In most cases, they predict that the impact type 1 diabetes has on health and direct costs of young people living with the disease is underestimated as most registries limit the recruitment of data by up to 14 years (Bruno, 2016). With an increase in prevalence each year, there is an increasing burden on the healthcare system translating into a lower quality of care for patients that are not supported with devoted personnel. This is particularly important among young people as they often have low compliance to intensive insulin treatments and adherence to scheduled visits. It is important to have a correct estimate on the prevalence of the disease, as well as the direct costs associated with type 1 diabetes. This will help health policymakers understand, plan, and improve treatments for the disease.

The Bruno study estimates an incidence rate of 16.1/100,000 people per year in Italy for type 1 diabetes. Prevalence of the disease in age group 0-29 increased from 137/100,000 in 2002 to 166.9/100,000 people in 2012.

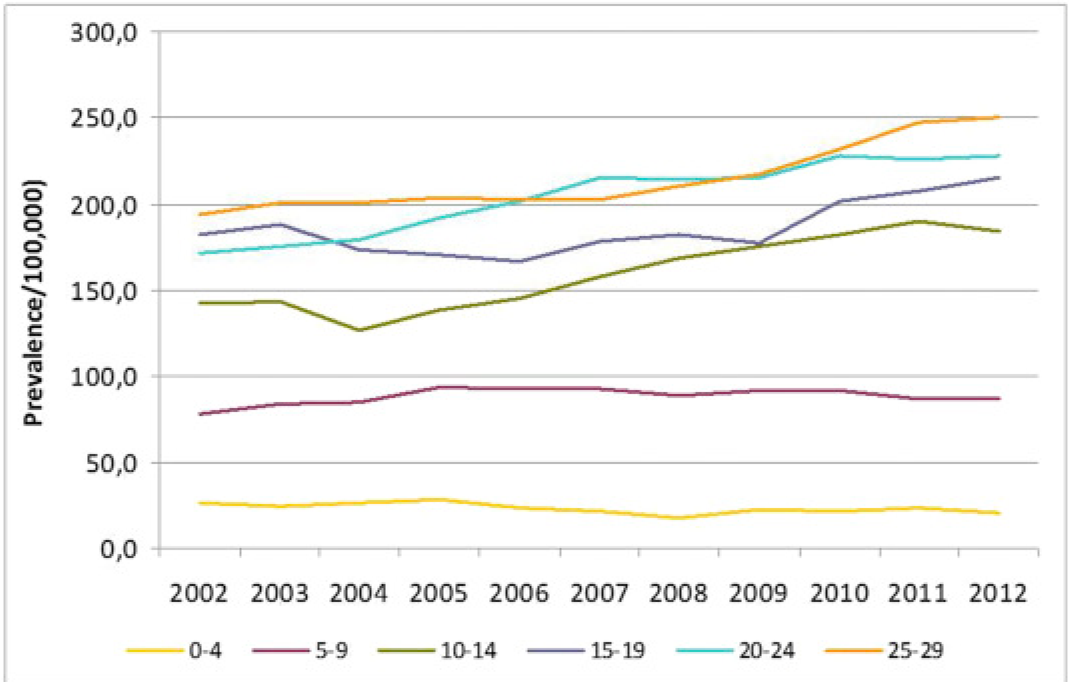


Figure 5. Prevalence of type 1 diabetes by 5-year age group, period 2002-2012, Italy (Bruno, 2016).

It can be seen from Figure 5 that the prevalence of type 1 diabetes was highest in the 25-29 age range and lowest in the 0-4 age range. This is to be expected as there are more people who develop type 1 diabetes each year, increasing the total number of cases within an age group. Figure 3 also shows how the number of diabetes cases has increased each year in age groups 10-14, 15-19, 20-24, and 25-29 years of age.

V. Prevalence of Diabetes in the United States

The CDC has been able to produce The National Diabetes Statistics Report, a periodic publication that provides information on the prevalence and incidence of diabetes and prediabetes, risk factors for complications, acute and long-term complications, deaths and costs in an effort to prevent and control diabetes across the United States (Centers for Disease Control and Prevention, 2020). This current update is for the year 2020. Among the United States population crude estimates for 2018 diagnosed and undiagnosed cases were that 34.2 million people of all ages, 10.5% of the United States population had diabetes. In addition, 34.1 million adults aged 18 years or older, or 13% of United States adults had diabetes. The next statistic is a little shocking, about 7.3 million adults aged 18 years or older who met the laboratory criteria for diabetes were not aware of even having diabetes, about 2.8% of the United States population. This suggests that better patient monitoring, screenings, and check-ups are necessary.

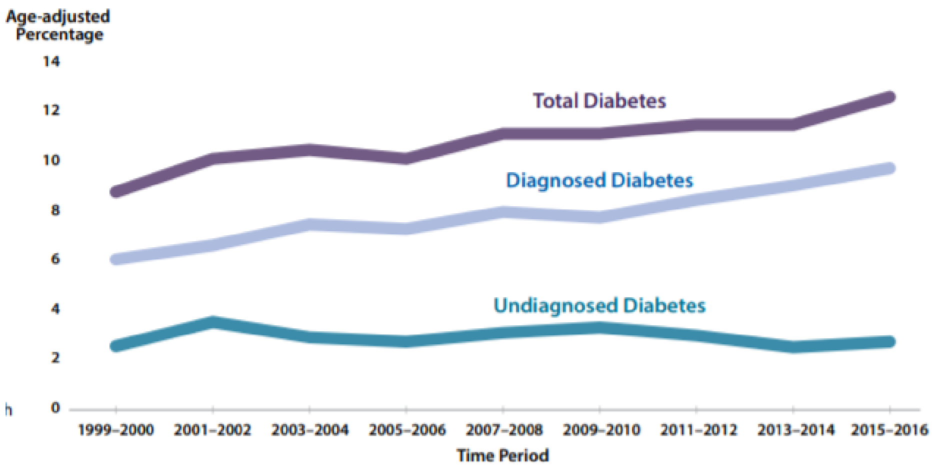


Figure 6. Trends in age-adjusted prevalence of diagnosed diabetes, undiagnosed diabetes and total diabetes among adults aged 18 years or older, United States, 1999-2016 (Centers for Disease Control and Prevention, 2020).

Figure 6 shows that the total from 1999-2016, the prevalence of total diabetes significantly increased among adults 18 years or older. Prevalence rates rose from 9.5% in 1999-2002 to 12% in 2013-2016. It seems the prevalence in undiagnosed diabetes did not undergo a significant change throughout the years on the graph.

In addition, 210,000 children and adolescents younger than age 20 years had diagnosed diabetes. This is equivalent to 25 per 10,000 youths. 187,000 of the children are living with type 1 diabetes. There are 1.4 million adults aged 20 years or older that reported having type 1 diabetes and using insulin. Additionally, 2.9 million adults aged 20 years or older reported using insulin within a year of their diagnosis.

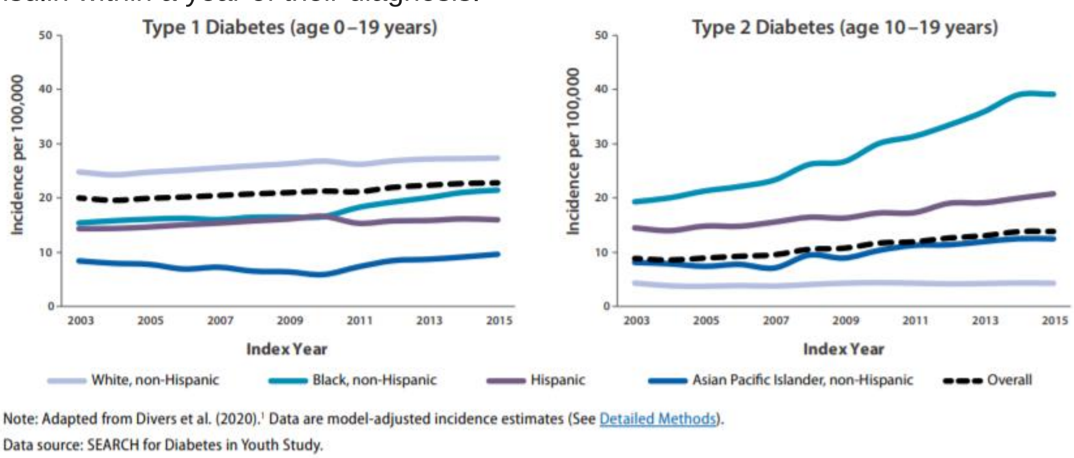


Figure 7. Trends in incidence of type 1 and type 2 diabetes in youth, overall and by race/ethnicity, 2002-2015 (Centers for Disease Control and Prevention).

Figure 7 shows that for the period 2002-2015, overall incidence of type 1 and type 2 diabetes significantly increased for children and adolescents aged less than 20 years of age; from 2002-2010, Hispanic children and youth had the largest significant increase in type 1 diabetes, while from 2011-2015 non-Hispanic Asian and Pacific Islander children and youth had the largest significant increase in type 1 diabetes; additionally, from 2002-2015, overall incidence of type 2 diabetes significantly increased.

Diabetes has potential to lead to complications as mentioned earlier and in 2016 a total of 16 million emergency department visits were reported with diabetes as the listed diagnosis. With the amount of money spent per patient this is very taxing to the individual and system as a whole. This puts strain on the hospitals around the country as these could be avoidable in many circumstances, e.g. when a patient has to come in for hyperglycemia. This is preventable in cases where the patient does not have access to insulin, and then the question becomes why doesn’t the patient have access to insulin? Hopefully not due to economic reasons, however this cannot be ruled out as 8.5% of the United States population does not have health insurance.

VI. The Cost of Diabetes

The cost of diagnosed diabetes in 2017 in the United States is $327 billion, $237 billion attributed to direct medical costs and $90 billion in reduced productivity (American Diabetes Association, 2018). Care for people with diagnosed diabetes accounts for 1 in 4 healthcare dollars in the United States. The average medical expenditures for people diagnosed with diabetes is $16,750 per year, of which around 9,600 is attributed to diabetes. Furthermore, people living with diabetes have at least 2.3 times higher than the medical expenditures of non-diabetic people. Additionally, the impacts of complication lead to $37.5 billion dollars lost because of disease-related disability and 277,000 premature deaths attributed to diabetes costing the economy $19.9 billion dollars (American Diabetes Association, 2018).

Many of the costs due to diabetes can be driven down by proper management of the disease. This requires a good patient-doctor relationship, in which the patient becomes educated on the disease and trusts the doctor in following their recommended therapies and treatments. This could immensely reduce the costs for both individuals and hospitals. Implementation of new technology like the CGM would also help patients maintain balanced blood glucose levels and avoid complications.

In Italy, studies conducted by Marcellusi *et al*. were performed to estimate the economic aspects in the management of diabetes in Italy. The results they obtained came from reported data in the Marche region in central Italy at the national level. The total economic burden of diabetes in Italy came to be 8.1 billion euro per year. The 8.1 billion euro was split up 22% for drugs, 74% hospitalizations and 4% for visits. The authors created a scenario analysis on how improvement of the general monitoring parameters condition the progression of diabetic complications. They used hypotheses based on expert opinions. The scenario analysis concluded that the implementation of good clinical practice and reduction of hospital visits by 25% could save 1.2 million euro.

The individual patient's costs are much lower than that of those living in the United States as nearly all the necessary drugs and diabetic equipment is provided by the Italian Health system. However, the equipment is not always the same regionally, leading towards some people paying more for the more advanced equipment. The bare minimum provided to diabetic citizens in Italy are syringes and insulin vials, as well as a glucose meter.

Table 6. Direct cost of diabetes to the Italian health system in 2012 in the prevalent cohort of type 1 diabetes in people aged 0-29 years (Marcellusi, 2016).

Direct cost in euro for person per year	Diabetic People (n = 2905)	Nondiabetic people (n = 11,620)	Change in %
Total Costs	2117 (1963 - 2252)	283 (262 - 303)	648%
Drugs	467 (437 - 497)	45 (36 -52)	938%
Insulin	347 (331-364)	0	-
Reagent (Glucose) strips (etc.)	715 (649 - 780)	0	-
Hospitalizations	679 (579-768)	154 (136 - 169)	327%
Outpatient examinations	256 (235-274)	84 (81 - 88)	193%

Table 6 works to show the cost and burden the disease has on the healthcare system. Examinations, consultations, and hospitalizations represent the reimbursement that was paid by the LHUs to healthcare providers. Drugs were valued with the public prices reimbursed by the NHS. Diabetic people had costs nearly 6-fold what the non-diabetic people faced. The economic burden is clear and only increasing each year as more people develop the disease. Hospitalizations decreased the older the patients were. This is representative of good healthcare and patients receiving education on diabetes, as well as the proper management supplies. The main costs of management being insulin and reagent strips.

VII. Conclusions on Diabetes and the Healthcare Systems

There are both pros and cons to health care systems in the United States and Italy. There are a multitude of differing opinions on the health care systems from people within their countries. For example, in a survey performed by the commonwealth fund in the US, 27% of respondents were in favor of eliminating all private health insurance, while 40% responded they did not have enough information. The rest of the citizens were content with the system that was in place. Furthermore, 43% of democrats favored replacing all private health insurance with a public plan, while only 12% of republicans and 27% of independents believed this to be necessary (Collins and Gunja, 2019). In a survey completed by the SSN in Italy, they deemed that patients' satisfaction with reference to healthcare service was remarkably high in the North, while reaching dissatisfaction rates of 85% in the South for some hospitals (Ferre *et al*. 2014).

The United States is the only profit motivated healthcare system in the world. Coincidently, or not so much, it also has the most expensive healthcare system in the world (Branning and Vater, 2016). The question to answer is why these costs are skyrocketing even more if the care is not quality of care is not improving. No part of the healthcare system wants to accept the blame as politicians are blaming pharmaceutical companies, who in turn blame healthcare insurers or pharmacy benefit managers. It seems that no one is truly happy with the way things are. Branning and Vater (2016) suggest this is because of the misaligned incentives shown in Table 7.

Table 7. Healthcare Stakeholders' Misaligned Incentives.

Patient	Spends as little out of pocket as possible. Relies on third-party payers for the majority of healthcare costs
Provider	Earns substantial income, enough to pay back student loans and justify the time and effort in patient care
Health Insurer	Generate more in revenue than the company spends on medical care for money
Pharmacy Benefit Manager	Collects service fees and earns a percentage of savings generated on behalf of customers
Government	Spends as little taxpayer money as possible while attempting to care for US' most at risk populations
Pharmaceutical manufacturer	Generates enough income to earn profit after recouping research and development and marketing costs

One of the biggest problems in the United States healthcare system is these misaligned incentives interfering with quality of car. All the stakeholders listed above in Table 7 can agree that the main concern is quality and cost-effective care for the patient, however there are other factors at play getting in the way. The degree that these factors get in the way can vary from stakeholder to stakeholder and cannot be applied universally. These factors and motivations are different for every stakeholder further driving up the cost.

In the United States, patients are usually the victims of the misaligned incentives of the healthcare system, but they do bear responsibility for rising costs as well. The patients do not value healthcare as a service in which they are willing to invest their own money upfront. They do not have incentives to participate in the system early to reduce the costs. Although people are being pushed towards high-deductible health plans that require a large payment up front, this does not always work. This approach can discourage patients from seeking help when they need necessary care when they don't deem it essential. A person should not feel discouraged from receiving healthcare due to economic reasons, for if they do not there may be even worse economic pains and health issues than the initial visit.

Looking at the case studies with diabetes, this type of situation can happen when a person has higher than normal blood glucose levels leading to ketosis or acidosis. They may be inclined not to go to the hospital even though their body is being slowly poisoned due to the costs of the visit, on top of the insulin they already must pay for. This can also happen in the circumstance of hypoglycemic emergency, or even when a person does not have enough insulin and cannot afford more. Studies indicate that insulin users had 1.24 times higher risk of cost related medication non-adherence compared to those not on insulin (Kang et al. 2018). The United States government's assumption that individuals know how to make rational decisions about buying health insurance plans is not well placed. There is little formal education on these plans and most people take the cheapest plans that ultimately may not benefit them. If the United States can lower the amount of hospitalizations and costs associated with discharge of patients, the system will benefit greatly. This can only be accomplished through good general practice, increasing health standards, providing better education regarding individual health and exercise, and more funding. In conclusion in Italy, the amount of daily exercise was greater than in comparison in the United States, leading to 28% less obesity and lower instances of diabetes.

In Italy, the health care system seems to be fairer to the patients, yet in reality there are still many disparities within the system. Offering free drugs to manage chronic diseases is a huge advantage for the at-risk populations. As seen in the case studies of diabetes, it runs in families and greatly affects them. For many people, if diabetes does not run in their family, they do not give it a second thought and can very negatively economically impact people as is the case with the United States. However, the regionally based system results in unfair treatment, especially benefitting people who live in the Northern regions. The Southern regions economy produces a much lower GDP in comparison to the North and the regionally based healthcare system reflects this. For example, in the North, diabetic citizens may receive a diabetic pump to treat their diabetes, while citizens in the South receive syringes and vials of insulin. Italy can benefit greatly from looking at their own system and identifying the issues that seemingly cause a huge divide in the quality of care from the North to the South. Interestingly, on average the south tends to spend a higher percentage of their GDP on healthcare. Further studies are warranted to indicate if this is due to people receiving worse equipment in the south leading to more hospitalizations increasing the spending or solely due to having a smaller GDP in the south.

Italy and the United States have similar methods of treatment. However, diabetes is more economically taxing for individuals who have the disease in the United States. In both countries there are budget cuts to funding of research being performed on diabetes as the number of cases are on the rise. Figure 6 highlights the United States government spending on diabetic research in the United States. Type 2 focused research increased by $240 million from $419 million to $659 million. Meanwhile research for type 1 and general diabetes research were nearly slashed in half dropping by $152 million and $122 million, respectively.

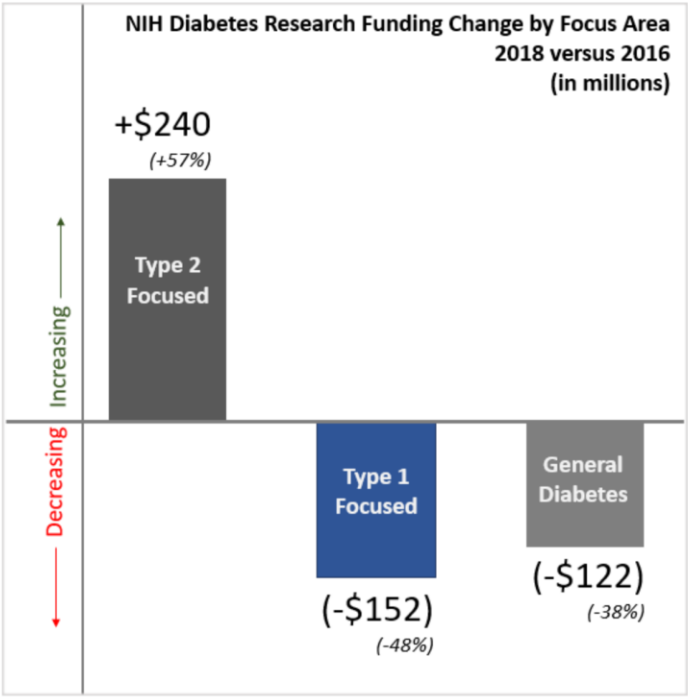


Figure 8. National Institute of Health's Diabetic Research Funding in 2018 vs 2016 (Juvenile Diabetes Care Alliance, 2019).

Italian research faces similar budget cutting problems. There is also the problem of doctors and drug makers being promised more funds, but due to politics and budget cuts, this has not happened. Some doctors are starting to feel underpaid and overworked. Drug makers feel there are not enough funds devoted to pricey and innovative drugs, as well as limited adoption of cheaper generics. Massimo Scaccabarozzi, the president of Farmindustria, Italy's main drug trade group has said "The government needs to acknowledge what a pivotal role we play for Italy, or drug makers will move somewhere else" (Paravicin, 2016).

The increasing rate of diabetes across the globe is associated with huge economic and human costs. This is troublesome, especially in some groups that are especially high at risk for developing the disease, such as indigenous populations in industrialized countries. There is a need for improvement regarding monitoring, care, and screening for diabetes across the globe to reduce diabetes related morbidity and mortality. People's lives are the most important aspect of society as society cannot exist without those lives. It is worth noting that diabetes in 2015 directly caused 1.6 million deaths, while in 2017 an estimated 4 million deaths were attributed to diabetes and its complications (Mohan, 2020).

There are solutions that can be implemented in the two countries today to improve patient satisfaction and drive down costs. Single use reagent strips to read blood glucose levels are not as efficient as can be, albeit it necessary. In today's world, the CGM is an extraordinary device and with proper funding and studies, it potentially can eliminate the need for reagent strips. This in the long run has potential to help the patient and help reduce costs and waste by producing less and less strips, instead focusing on the technology that can improve lives. The CGM allows the patient to always keep track of blood glucose and prevent hyperglycemic or hypoglycemic attacks. This would reduce hospitalizations and prevent complications, which is invaluable for the patients. Furthermore, the happier a patient is, the more likely they are to respond positively to proper management of a disease like diabetes. The CGM is an example of how funding for diabetic research is ultimately one of the only things that can help benefit diabetic individuals and governments a lot of money and health crises.

Health care systems have been around for centuries, they are not something that has recently been devised. There are written records and physical remains found in Deir el-Medina in Egypt revealing the first known governmental health care system running. This was in 1292 B.C. As technology became more prevalent in the 19th century from inventions like the thermometer, stethoscope, vaccination, anesthesia and more, there has been a desire to expand medical knowledge. Clinical researches were encouraged to specialize because this specialization leads to a deeper knowledge. The healthcare systems today mirror the 200-year old model of factory outlined by Adam Smith with specialists playing the role of pin makers (Anderlini, 2018). The problem with this approach is that human bodies are not the equivalent of a pin or an automobile. Although humans can split a job into smaller parts, we are not able to split a human patient into smaller parts without losing some part of the whole view (Anderlini, 2018).

Although doctor specialization leads to a deeper knowledge of organs and organ systems, oftentimes there are key parts a doctor who specializes in one field may miss that pertains to another. There can also be a lack of communication between specialists leading to redundant testing and a lack of knowledge on how specific therapies interact with others (Anderlini, 2018). Improved communication between specialists will benefit the patient and drop costs.

Another issue is the barrier between scientists and clinicians, who each have specialized in fields that dull the ability to communicate effectively. They also lack a common value system; doctors deal with life and death while scientists do not. For example, pharmaceutical companies are starting to pull out of research into Alzheimer’s as 99% of trials for Alzheimer’s drugs have failed in the past 15 years. There is a need for more funding towards these kinds of research as they can potentially prevent disease progression and complications, making the funding more valuable.

As the number of cases of diabetes and other chronic diseases rises each year, the direct and indirect costs of such diseases will drive up overall healthcare spending. Governments have choices to make, either keep letting the problems grow or attend to the needs of solving the health systems crises. Problems include the increasing economic costs, equity of treatments, and funding while combating the rising national debts. If not, the economic costs and toll to human health will be immense.

VIII. References

Ali O. 2010. Type 1 diabetes mellitus: Epidemiology, genetics, pathogenesis, and clinical manifestations. In: Principles of diabetes mellitus. Boston, MA: Springer US. 181 p.

American Diabetes Association. 2018. Economic costs of diabetes in the U.S. in 2017. Diabetes Care. 41(5):917-28.

Anderlini D. 2018. The United States healthcare system is sick: From Adam Smith to overspecialization. Cureus. 10(5):e2720.

Anderson, Steve. 2018. Private health insurance: The American way for nearly 100 years [Internet]; c2018 [cited 2020 May]. Available from: https://www.healthinsurance.org/obamacare/private-health-insurance/ .

Berchick E, Barnett J, Upton J. 2019. Health insurance coverage in the United States: 2018. United States Government.

Branning G, Vater M. 2016. Healthcare spending: Plenty of blame to go around. American Health & Drug Benefits. 9(8):445-7.

Bruno G, Pagano E, Rossi E, Cataudella S, De Rosa M, Marchesini G, Miccoli R, Vaccaro O, Bonora E. 2016. Incidence, prevalence, costs and quality of care of type 1 diabetes in Italy, age 0–29 years: The population-based CINECA-SID ARNO observatory, 2002–2012. Nutrition, Metabolism and Cardiovascular Diseases. 26(12):1104-11.

Cauchi R, Mason K, Chung Y, Thangasamy A. 2016. Diabetes health coverage: State laws and programs. Denver, Colorado: National Conference of State Legislators.

Centers for Disease Control and Prevention. 2020. National diabetes statistics report 2020. Atlanta, GA: Centers for Disease Control and Prevention.

Donatini, Andrea. 2016. The Italian Health Care System [Internet]; c2016 [cited 2020]. Available from: https://international.commonwealthfund.org/countries/italy/ .

Ferre F, de Belvis AG, Valerio L, Longhi S, Lazzari A, Fattore G, Ricciardi W, Maresso A. 2014. Italy: Health system review. Health Systems in Transition. 16(4):1.

Fu Z, Gilbert ER, Liu D. 2013. Regulation of insulin synthesis and secretion and pancreatic beta-cell dysfunction in diabetes. Current Diabetes Reviews. 9(1):25.

Himabindu B, Madhu P, Reddy PS. 2015. Diabetes and alcohol: Double jeopardy with regard to oxidative toxicity and sexual dysfunction in adult male wistar rats. Reproductive Toxicology. 51:57-63.

Jameson JL, Kasper DL, Longo DL, Fauci AS, Hauser SL, Loscalzo J, Harrison TR. 1998. Harrison's principles of internal medicine. 17th edition ed. New York; Chicago; San Francisco: McGraw Hill Education.

Juvenile Diabetes Cure Alliance. 2019. NIH T1D Funding Cut in Half [Internet]; c2019 [cited 2020]. Available from: http://thejdca.org/nih-funding-cut-in-half.

Kang H, Lobo JM, Kim S, Sohn M. 2018. Cost-related medication non-adherence among U.S. adults with diabetes. Diabetes Research and Clinical Practice. 143:24-33.

Marcellusi A. 2016. The direct and indirect cost of diabetes in Italy. The European Journal of Health Economics. 17(2):139-47.

Ministero della Salute. 2019. Cure nell'Unione Europea [Internet]; c2019 [cited 2019 5/4]. Available from: http://www.salute.gov.it/portale/cureUE/homeCureUE.jsp.

Paravicin G. 2016. Troubled Italian health system frustrates doctors, drugmakers. Politico Europe.

Röder PV, Wu B, Liu Y, Han W. 2016. Pancreatic regulation of glucose homeostasis. Experimental & Molecular Medicine. 48(3):e219.

Rohit N. Kulkarni, C. Ronald Kahn. 2004. HNFs: Linking the liver and pancreatic islets in diabetes. Science. 303(5662):1311-2.

Sara R Collins, Munira Z Gunja. 2019. What do Americans think about their health coverage ahead of the 2020 election? New York: Aspen Publishers, Inc. Report nr 36. 9 p. .

Silvers JB. 2013. The affordable care act: Objectives and likely results in an imperfect world. Annals of Family Medicine. 11(5):402-5.

Stumetz KS, Yi-Frazier JP, Mitrovich C, Briggs Early K. 2016. Quality of care in rural youth with type 1 diabetes: A cross-sectional pilot assessment. BMJ Open Diabetes Research & Care. 4(1):e000300.

The U.S. Healthcare System [Internet]; c2020. Available from: https://international.commonwealthfund.org/countries/united_states/ .

World Health Organization. 2020. Italy [Internet]; c2020. Available from: http://www.euro.who.int/en/countries/italy .